

§ 882.5910

used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

(b) *Classification.* Class II (performance standards).

§ 882.5910 Dura substitute.

(a) *Identification.* A dura substitute is a sheet or material that is used to repair the dura mater (the membrane surrounding the brain).

(b) *Classification.* Class II (performance standards).

§ 882.5940 Electroconvulsive therapy device.

(a) *Identification.* An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987]

§ 882.5950 Artificial embolization device.

(a) *Identification.* An artificial embolization device is an object that is placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987]

§ 882.5960 Skull tongs for traction.

(a) *Identification.* Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored

21 CFR Ch. I (4-1-98 Edition)

to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

(b) *Classification.* Class II (performance standards).

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart A—General Provisions

Sec.

884.1 Scope.

884.3 Effective dates of requirement for premarket approval.

884.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Obstetrical and Gynecological Diagnostic Devices

884.1040 Viscometer for cervical mucus.

884.1050 Endocervical aspirator.

884.1060 Endometrial aspirator.

884.1100 Endometrial brush.

884.1175 Endometrial suction curette and accessories.

884.1185 Endometrial washer.

884.1300 Uterotubal carbon dioxide insufflator and accessories.

884.1425 Perineometer.

884.1550 Amniotic fluid sampler (amniocentesis tray).

884.1560 Fetal blood sampler.

884.1600 Transabdominal amnioscope (fetoscope) and accessories.

884.1630 Colposcope.

884.1640 Culdoscope and accessories.

884.1660 Transcervical endoscope (amnioscope) and accessories.

884.1690 Hysteroscope and accessories.

884.1700 Hysteroscopic insufflator.

884.1720 Gynecologic laparoscope and accessories.

884.1730 Laparoscopic insufflator.

Subpart C—Obstetrical and Gynecological Monitoring Devices

884.2050 Obstetric data analyzer.

884.2225 Obstetric-gynecologic ultrasonic imager.

884.2600 Fetal cardiac monitor.

884.2620 Fetal electroencephalographic monitor.

884.2640 Fetal phonocardiographic monitor and accessories.

884.2660 Fetal ultrasonic monitor and accessories.

884.2675 Fetal scalp circular (spiral) electrode and applicator.

884.2685 Fetal scalp clip electrode and applicator.

884.2700 Intrauterine pressure monitor and accessories.